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EXAMINER

LOEB, BRONWEN

ART UNIT PAPER NUMBER

1636

DATE MAILED: 02/28/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/227,742

Applicant(s)

BLOOM ET AL.

Examiner

Bronwen M. Loeb

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 45-59 and 61-84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-59 and 61-84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 21.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to the amendment filed 5 December 2001 in which claims 45-48, 50, 52-55, 58, 59, 61, 62 and 64-68 were amended, claim 60 was cancelled and new claims 72-84 were presented.

Claims 45-59 and 61-84 are pending.

### ***Oath/Declaration***

1. Applicant's desire to continue to hold the matter of the Oath/Declaration in abeyance is noted; however, the present Oath/Declaration remains defective for the reasons made of record in the Office action mailed 12 April 1999, Paper #2.

### ***Claim Objections***

2. Claims 70 and 71 are objected to because of the following informalities: In both claims 70 and 71, the word "enhanced" is misspelled. Appropriate correction is required.

***Response to Amendment***

3. The rejection of claims 45-53, 58-65, 70 and 71 under 35 USC §112, first paragraph, scope of enablement, has been withdrawn in view of Applicant's amendment.

The rejection of claims 45-57 under 35 USC §112, first paragraph (new matter) has been withdrawn in view of Applicant's amendment.

The rejection of claims 58-70 under 35 USC §102(b) as being anticipated by de Mendoza et al (JBC or TIBS reference) has been withdrawn in view of Applicant's amendment.

The rejection of claims 58, 59, 63-67 and 71 under 35 USC §102(b) as being anticipated by Inoue et al has been withdrawn in view of Applicant's amendment.

4. Claims 45-59 and 61-71, and newly added claims 81-84, stand rejected under the judicially created doctrine of obviousness-type double patenting for the reasons made of record in the Office actions mailed 22 September 1999, 5 June 2000 and 5 June 2001. Applicant's willingness to file a Terminal Disclaimer (p. 4, amendment filed 5 December 2000) is noted; however the rejection is maintained in the absence of said disclaimer.

5. New grounds of rejection, necessitated by Applicant's amendment, are presented below.

**New Grounds of Rejection**

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 72 and 80 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is based on the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. §112, first paragraph "Written Description" Requirement published in the Federal Register (Volume 64, Number 244, Pages 71427-71440). Claim 80 is drawn to a competent *E. coli* having an increased unsaturated fatty acid content relative to total fatty acid content wherein said increased unsaturated fatty acid content is caused by genetically selecting for a bacterium having an increased membrane unsaturated fatty acid content. This is a genus claim in terms of any mutation that increases membrane unsaturated fatty acid content. The specification mentions strain SB3499. This disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all of the spontaneous mutations that increase membrane unsaturated fatty acid content in *E. coli* based on the teachings in the specification. Strain SB3499 is a mutant strain generated by cycling. The genetic basis

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for its increased membrane unsaturated fatty acid content is not discussed or explored. It is unknown whether it bears a single mutation or a multitude of mutations to several different genes. Therefore, the specification does not describe the claimed genus of competent *E. coli* in such full, clear, concise and exact terms so as to indicate that Applicant has possession of these competent *E. coli* at the time of filing the present application. Thus, the written description requirement has not been satisfied.

8. The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 72-80 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 72 is vague and indefinite as it unclear what "enhanced transformation ability" is compared to.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 72, 76 and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Bogoslovakaia et al (Zh. Mikrobiol. Epidemiol. Immunobiol. (1984) 12:65-68).

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Bogoslovakaia et al teach *E. coli* having an increased unsaturated fatty acid content relative to total fatty acid content. See Abstract and the Table on p. 66. Enhanced transformation ability after storage at a temperature of from about 4°C to about -20°C is an inherent property of such bacteria. Discovery of a new property of a previously known composition, even if unobvious from prior art, cannot impart patentability to claims of known composition. *In re Spada* 15 USPQ2d 1655 (CAFC, 1990).

### **Conclusion**

Claims 45-59 and 61-84 are rejected.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.


Any inquiry of a general nature or relating to the status of this application should be directed to Tracey Johnson, Patent Analyst whose telephone number is (703) 305-2982.

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Bronwen M. Loeb, Ph.D.  
Patent Examiner  
Art Unit 1636

February 22, 2002

  
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